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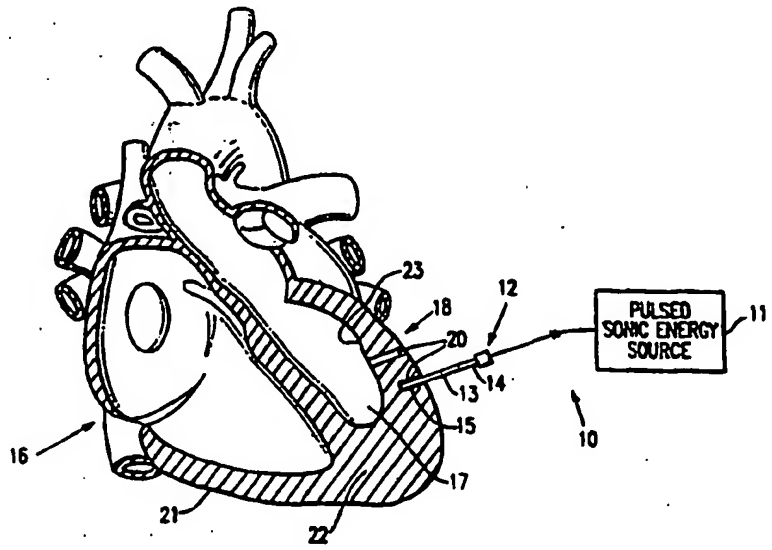
(54) Title: SYSTEM AND METHOD OF INTRA-OPERATIVE MYOCARDIAL REVASCULARIZATION USING PULSED SONIC ENERGY



(57) Abstract

The method for ablating tissue of a patient's heart comprising, providing a pulsed sonic energy apparatus with an elongated probe member. The probe member contacts the patient's heart tissue, and heart tissue is ablated by bursts of pulsed sonic energy transmitted through the probe member. Also provided is a system for forming a channel in a patient's heart wall, comprising an elongated probe member connected to a source of bursts of pulsed sonic energy. During ablation or channel formation, the energy bursts are delivered in a timed sequence, which may be either dependent or independent of the patient's heart cycle.

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SYSTEM AND METHOD OF INTRA-OPERATIVE MYOCARDIAL REVASCULARIZATION USING PULSED SONIC ENERGY

BACKGROUND OF THE INVENTION

This invention generally relates to the field of heart tissue removal, and more particularly to the use of pulsed sonic energy for myocardial revascularization to improve the flow of blood to the heart muscle and cure angina.

Myocardial revascularization typically involves formation of one or more channels in a patient's heart wall defining the heart chamber to treat a patient's ischemic myocardial tissue therein. The first trials of the revascularization process was made by Mirhoseini *et al.* See for example the discussions in Lasers in General Surgery (Williams & Wilkins; 1989), pp 216-223. Another early disclosure of this procedure is found in U.S. Patent 4,658,817 (Hardy). Both of these references describe laser myocardial revascularization (LMR) procedures in which a laser is used to form the revascularization channels through the epicardium, myocardium and endocardium.

One disadvantage of LMR is the high cost of the laser based systems. It would be a substantial advance if a low cost yet reliable myocardial revascularization system was available. The present invention satisfies these and other needs.

SUMMARY OF THE INVENTION

The present invention generally involves use of a pulsed sonic energy apparatus for the removal of heart tissue, including both the ablation of the tissue and the formation of channels in the tissue. One aspect of the invention provides a method for ablating tissue of a patient's heart comprising, providing a pulsed sonic energy apparatus with an elongated probe member. The probe member contacts the patient's heart tissue, and transmits bursts of pulsed sonic energy to the heart tissue. Also provided is a system for forming a channel in a patient's heart wall, comprising an elongated probe member connected to a source of bursts of pulsed sonic energy. The transverse dimension, or diameter, of the probe member is essentially the same as the size of the channel to be formed.

During ablation or channel formation, the energy bursts are delivered in a timed sequence, which may be either dependent or independent of the patient's heart cycle. By providing the sonic energy bursts at a specific frequency and pulse duration, the removal of the heart tissue can be optimally controlled. These and other advantages of the invention will become more apparent from the following detailed description of the invention and the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic section of a human heart showing revascularization of the myocardium according to the invention.

Fig. 2 is a schematic block diagram of a pulsed sonic energy system synchronized to a heart beat according to the invention.

DETAILED DESCRIPTION OF THE INVENTION

As shown in the drawings, which are provided for purposes of illustration and not by way of limitation, an apparatus suitable for implementing the present invention is embodied in a system for revascularization of the myocardium of a human heart 16. While the invention is discussed in terms of myocardial revascularization, it should be understood that the invention includes the ablation of heart tissue as well.

As illustrated in Fig. 1, a pulsed sonic energy generator 10 of the invention generally comprises a source of pulsed sonic energy 11 and a transmitting device 12 including an elongated probe member 13. In the basic method of the present invention, the elongated probe member 13 is inserted into the chest cavity. This insertion may require only a small incision, which would minimize the invasiveness of the procedure. Elongated probe member 13 is then placed in contact with an area of the heart 16, such as a ventricle 17, having an area 18 in need of increased blood circulation due to cardiovascular disease. Portions of the heart other than ventricles 17 might also be revascularized by this method. Pulsed sonic energy is transmitted in a plurality of bursts through the elongated probe member 13 of the transmitting device 12 to the patient's heart tissue in contact therewith. A number of channels 20 can then be formed by the elongated probe member 13 from the outer wall, or

epicardium 21, and extend through the myocardium 22. The channel can optionally perforate the interior of the heart wall, or endocardium 23.

In one embodiment of an apparatus adapted for the present method, the elongated probe member 13 is shaped to facilitate contact with a region of the patient's heart, e.g. with a bend, into a desired configuration (not shown).

One aspect of the invention provides a system for forming a channel of desired transverse dimensions in a wall of a patient's heart. The system comprises an elongated probe member 13, a source of a plurality of bursts of pulsed sonic energy 11, and means to connect the source 11 to the proximal extremity of the probe member 13. In practice, it has been found that the elongated probe member 13 having a proximal end 14 and a distal end 15, when in contact with tissue, cuts a channel essentially equal to the transverse dimension of the probe member distal end 15. In one aspect of the invention, the means to connect the pulsed sonic energy source 11 has a handle means (not shown) to enable an operator to press the distal extremity of the probe member 13 into contact with the patient's heart wall to form a channel. The handle means facilitates pressing the probe member distal extremity perpendicularly against the patient's heart wall.

The heart beat is preferably monitored, and the sonic energy source 11 is preferably gated to generate one or more pulses during contractions (systole) of the heart, and to generate no pulses during the rest of the heart cycle. The presently preferred pulse duration is no more than 100 milliseconds. A plurality of bursts of pulsed sonic energy may be required to complete the channel 20 in the heart wall. The presently preferred frequency of the pulsed sonic energy emitted from the pulsed sonic energy source is at least 15,000 Hz. The sonic energy includes, for example, ultrasound, and the presently preferred source of pulsed sonic energy is an ultrasonic generator. The ultrasound generator drives a transducer operating at resonance coupled to the elongated probe member 13.

In accordance with one aspect of the invention, pulsed sonic energy is delivered to the heart tissue in a sequence dependent on the patient's heart beat cycle. The R wave is one of four distinct waveforms that exist in each heart beat cycle. Fig. 2 illustrates a schematic block diagram of a pulsed sonic energy system in which a +5 volt pulse is produced from an ECG monitor 31 for each R wave of a

beating heart. The ECG +5 volt pulse is sent to a one shot trigger generator 32, where it triggers a variable width pulse. The variable width pulse is typically no greater than 100 msec, and is sent from the one shot 32 to a NAND gate 33. When the system is turned on, the NAND gate 33 switch will close, in response to the variable width pulse from the one shot. The closed NAND gate sends a signal to a NPN transistor 34, which in turn energizes a reed relay 36, which triggers an ultrasonic generator 38 for a time that approximates the pulse width of the one shot. A foot switch connector may be provided so that the physician may selectively energize the elongated probe member 13 with ultrasonic energy for the formation of channels 20. The ECG monitor 31 may be a standard model, such as is available from Hewlett-Packard Company. The one shot trigger generator 32 and NAND gate 33 may be readily obtainable models, such as National Semiconductor models CD4047 BM, and CD 4011 BM respectively. The ultrasound generator 38 may be, for example, the MISSONIX generator, or another readily obtainable generator.

In operation, the distal end of the elongated probe member 13 may be maintained in position on the outer heart wall by a gentle pressure that advances the elongated probe member, to insure that the member 13 is not dislodged in the formation of the channel 20 between pulses of the sonic energy. As mentioned above, as few as one pulse of sonic energy per heartbeat is transmitted to the heart tissue. These procedures combine to anchor the pulsed sonic energy generator apparatus 10 to a relatively stable location on the heart tissue.

It has been found that an energized probe member 13 contacting the heart surface at a non-perpendicular angle has an increased risk of producing a heart arrhythmia. In operation, the elongated probe member 13 is held by the operator at an angle of approximately 90° to the heart surface. Alternatively, the elongated probe member is maintained in the perpendicular orientation relative to the surface of the beating heart by an orientation means (not shown). The orientation means comprises for example, a track in which the elongated probe member 13 proximal end 14 slides, wherein the probe member distal end 15 extends beyond the distal end of the tract and into the patient. With the track immobilized outside of the patient in a perpendicular orientation to the heart, the elongated probe member 13 is free only to move in a perpendicular orientation relative to the heart surface.

While the present invention has been described herein in terms of certain preferred embodiments those skilled in the art will recognize that modifications and improvements may be made to the invention without departing from the scope thereof.

WHAT IS CLAIMED IS:

1. A method for ablating tissue of a patient's heart comprising:

a) providing a pulsed sonic energy generator which includes a source of pulsed sonic energy and a transmitting device including an elongated probe member for delivery of pulsed sonic energy to tissue of a patient's heart;

b) contacting tissue of the patient's heart with the elongated probe member; and

c) transmitting pulsed sonic energy in a plurality of bursts through the elongated probe member of the transmitting device to the patient's heart tissue in contact therewith.

2. The method of claim 1 further including the step of advancing the elongated probe member to maintain the contact with the heart tissue during ablation.

3. The method of claim 1 wherein the bursts of pulsed sonic energy are delivered to the heart tissue in a timed sequence independent of the patient's heart beat cycle.

4. The method of claim 1 wherein the bursts of pulsed sonic energy are delivered to the heart tissue in a timed sequence dependent on the patient's heart beat cycle.

5. The method of claim 1 wherein the pulsed sonic energy has a frequency of at least 15,000 Hz.

6. The method of claim 1 wherein the pulse duration is no more than 100 milliseconds.

7. A system for forming a channel of desired transverse dimensions in a wall of a patient's heart, comprising:

a) an elongated probe member having a proximal extremity and a distal extremity with the latter having transverse dimensions essentially the same as the transverse dimensions of the channel to be formed in the patient's heart wall; and

b) a source of a plurality of bursts of pulsed sonic energy; and

c) means to connect the source of pulsed sonic energy to the proximal extremity of the probe member.

8. The system of claim 7 wherein the source of pulsed sonic energy is an ultrasonic generator driving a transducer operating at resonance coupled to a resonance probe.

9. The system of claim 7 wherein the pulse duration is no more than 100 milliseconds.

10. The system of claim 7 wherein the pulsed sonic energy source emits pulsed sonic energy at a frequency greater than 15,000 Hz.

11. The system of claim 7 wherein the means to connect the pulsed sonic energy source has a handle means to enable an operator to press the distal extremity of the probe member into contact with the patient's heart wall to form a channel therein.

12. The system of claim 11 wherein the handle means facilitates pressing the distal extremity of the probe member perpendicularly against the patient's heart wall.

13. The system of claim 7 wherein the elongated probe member is shaped with a bend to facilitate contact with the heart.

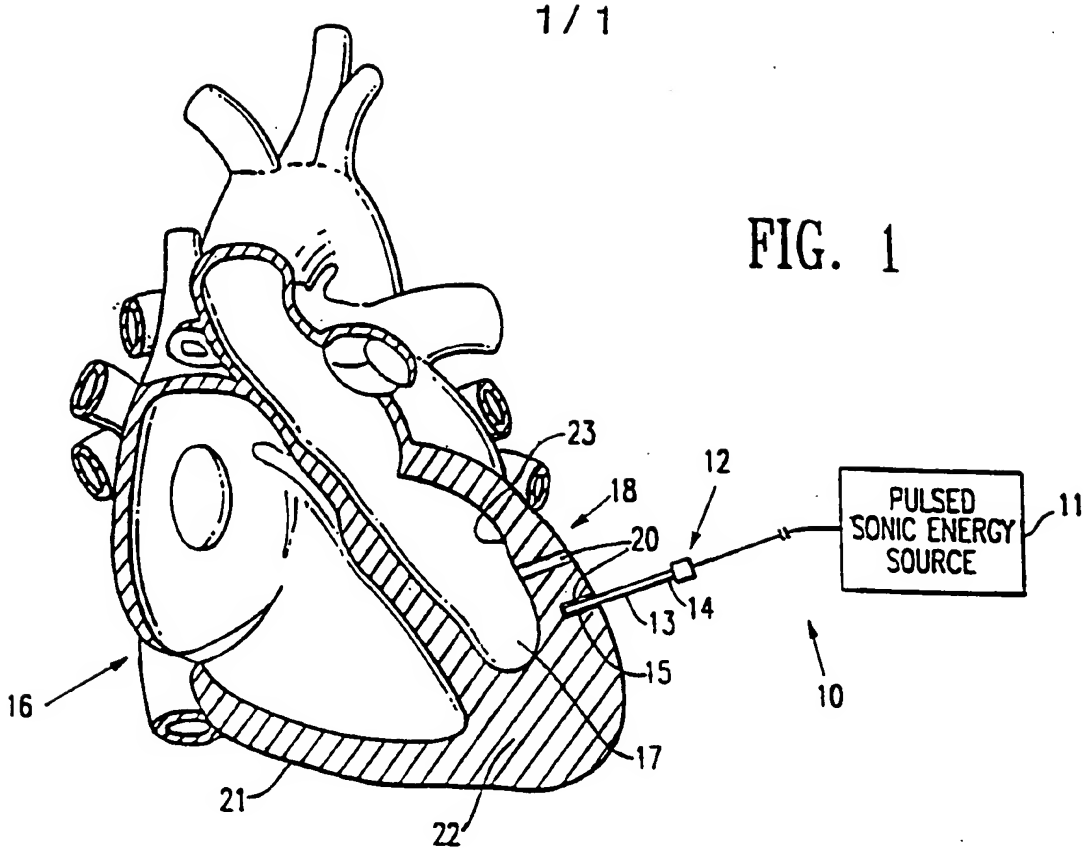
PULSED SONIC ENERGY SOURCE
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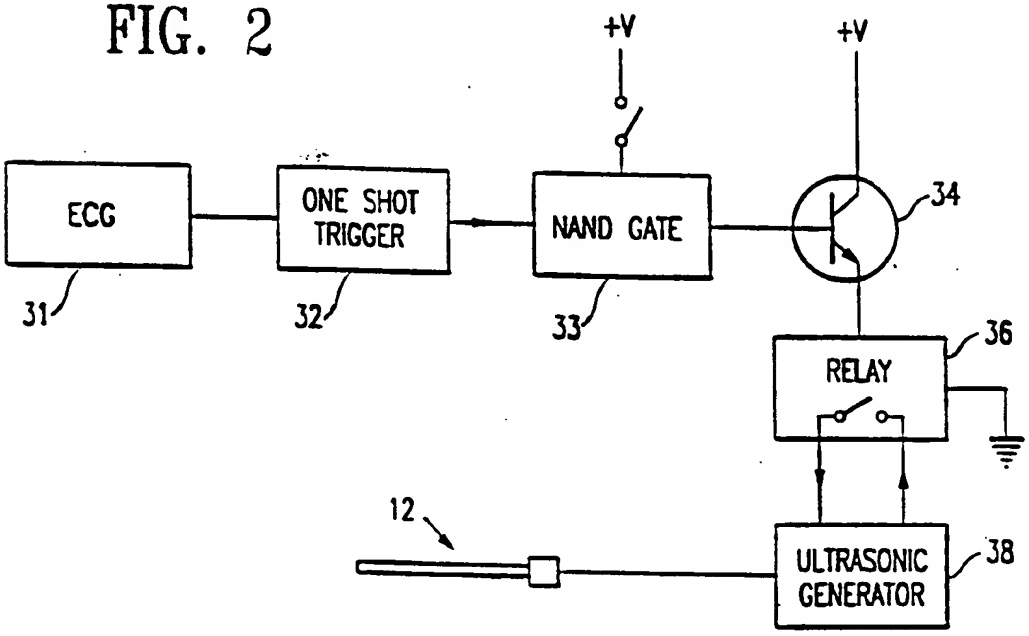
FIG. 1

FIG. 2


+V
+V
ECG
ONE SHOT TRIGGER
NAND GATE
34
31
32
33
RELAY
36
12
ULTRASONIC GENERATOR
38

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/US 98/16528

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/22

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 87 05793 A (COOPER LASERSONICS) 8 October 1987 see the whole document ---	7
X	WO 96 29935 A (BOSTON SCIENTIFIC CORP.) 3 October 1996 see page 7, line 14 - page 8, line 10; claim 1 ---	7
X	WO 94 06355 A (CORAJE) 31 March 1994 see abstract; claims 1,11,20-24,32,37 ---	7
X	US 4 936 281 A (STASZ) 26 June 1990 see column 4, line 40 - column 5, line 7 see column 6, line 5 - line 38; claim 1 ---	7

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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Date of the actual completion of the international search	Date of mailing of the international search report
18 November 1998	25/11/1998

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 310 431 A (CAVITRON) 5 April 1989 see column 3, line 33 - column 7, line 20; claim 1	7
X	WO 92 11815 A (BAXTER INTERNATIONAL ET AL.) 23 July 1992 see abstract see page 27, line 10 - line 14	7
E	US 5 827 203 A (NITA) 27 October 1998 see the whole document	7-13

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INTERNATIONAL SEARCH REPORT

In ational application No.
PCT/US 98/ 16528

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1-6
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1 (iv)- Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte onal Application No
PCT/US 98/16528

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 8705793 A	08-10-1987	US 4827911 A	09-05-1989
		CA 1322226 A	14-09-1993
		DE 3788099 D	16-12-1993
		DE 3788099 T	03-03-1994
		EP 0261230 A	30-03-1988
		JP 7106208 B	15-11-1995
		JP 63502968 T	02-11-1988
WO 9629935 A	03-10-1996	US 5630837 A	20-05-1997
		AU 5382296 A	16-10-1996
		EP 0764004 A	26-03-1997
		JP 10502290 T	03-03-1998
WO 9406355 A	31-03-1994	US 5362309 A	08-11-1994
		US 5318014 A	07-06-1994
		AU 4858093 A	12-04-1994
		EP 0664686 A	02-08-1995
		JP 8501238 T	13-02-1996
		US 5474531 A	12-12-1995
US 4936281 A	26-06-1990	NONE	
EP 310431 A	05-04-1989	US 4931047 A	05-06-1990
		AT 113457 T	15-11-1994
		AU 616699 B	07-11-1991
		AU 2538288 A	18-04-1989
		CA 1323665 A	26-10-1993
		DE 3852005 D	08-12-1994
		DE 3852005 T	09-03-1995
		DK 261589 A	29-05-1989
		ES 2064360 T	01-02-1995
		IE 67810 B	01-05-1996
		JP 6042893 B	08-06-1994
		JP 2501894 T	28-06-1990
		NO 300755 B	21-07-1997
		WO 8902725 A	06-04-1989
		US 5015227 A	14-05-1991
WO 9211815 A	23-07-1992	US 5304115 A	19-04-1994
		EP 0566656 A	27-10-1993

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 98/16528

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9211815 A		EP 0835644 A	15-04-1998
		JP 6507081 T	11-08-1994
		US 5368557 A	29-11-1994
		US 5368558 A	29-11-1994
		US 5397301 A	14-03-1995
		US 5447509 A	05-09-1995
		US 5380274 A	10-01-1995
		US 5474530 A	12-12-1995
		US 5542917 A	06-08-1996
		US 5540656 A	30-07-1996
		US 5267954 A	07-12-1993
		US 5326342 A	05-07-1994
		US 5312328 A	17-05-1994
		US 5324255 A	28-06-1994
US 5827203 A	27-10-1998	NONE	